

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

**David Hung et al.**

Atty. Docket: 005284.00198

Examiner: Unknown

Group Art Unit: Unknown

Serial No.: To Be Assigned  
(Division of Serial No.: 09/313,463)

Filed: June 30, 2003

For: Methods For Identifying Treating Or Monitoring Asymptomatic Patients  
For Risk Reduction Or Therapeutic Treatment Of Breast Cancer

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

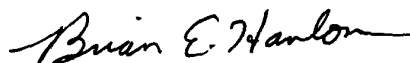
Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. § 1.56(a) Applicants submit herewith the references cited on the attached PTO-1449 forms.

Copies of these references are not submitted herewith, but can be found in parent application file U.S. Serial No. 09/313,463.

Applicants respectfully request that the Examiner consider these references in connection with the search of the prior art required by 37 C.F.R. § 1.104.

It is believed that no fee is required to ensure consideration of the cited references by the Examiner. However, if a fee is deemed necessary, the Commissioner is authorized to charge our Deposit Account No. 19-0733.

Respectfully submitted,



Brian E. Hanlon  
Reg. No. 40,449

Date: 6/30/03  
Banner & Witcoff, Ltd.  
Eleventh Floor  
1001 G Street, N.W.  
Washington, D. C. 20001-4597  
(202) 824-3000

Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet

**Complete if Known**

Application Number

To Be Assigned

Filing Date

June 30, 2003

First Named Inventor

David Hung

**Group Art Unit**

Unknown

Examiner Name

Unknown

Attorney Docket Number

005284.00198

[illegible][illegible]

Examiner  
Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO		<b>Compleat if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	To Be Assigned
		Filing Date	June 30, 2003
		First Named Inventor	David Hung
		Group Art Unit	Unknown
		Examiner Name	Unknown
		Attorney Docket Number	005284.00198
Sheet		of	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		PETRAKIS, N. L., "Oestrogens And Other Biochemical And Cytological Components In Nipple Aspirates Of Breast Fluid : Relationship To Risk Factors For Breast Disease", XP008013933, Proceedings of the Royal Society of Edinburgh, Biological, Vol. 95B, pp 169-181, dated 1989	
		BULUN, Serdar E. et al., "Endocrine Disorders Associated With Inappropriately High Aromatase Expression", XP-001148711, Journal of Steroid Biochemistry and Molecular Biology, Vol. 61, No. 3-6, pp 133-139, Dated April 1997	
		PANSERA, F., "Accessibility and possibility of elimination of breast epithelium: The theoretical possibility of preventing breast carcinoma through destruction of the epithelium of origin" Medical Hypothesis, Vol. 33, pp. 107-111, dated 1990	
		HOU et al., "A simple method of duct cannulation and localization for galactography before excision in patients with nipple discharge", Radiology, Vol. 195, pp 568-569, dated 1995	
		PETRAKIS, Cancer Epidemiology, Biomarkers, and Prevention, Vol. 3, pp. 3-10, dated February 1993	
		KING et al., Journal of the National Cancer Institute, Vol. 71/6, pp. 1115-1121, dated December 1983	
		GRESE et al, Current Pharmaceutical Design, Vol. 4, pp. 71-92, dated 1998	
		AZAVEDO et al, Anticancer Research, Vol. 6, pp 263-266, dated 1986	

Examiner Signature		Date Considered	
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FORM PTO-1449 (Modified)		Attorney Docket No.: 005284.00198		Application No.: TBA		
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: David Hung				
		Filing Date: June 30, 2003		Group: Unknown		
Reference Designation		U.S. PATENT DOCUMENTS				
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
AA	3,608,540	09/28/71	Sartorius			
AB	3,786,801	01/22/74	Sartorius			
AC	5,478,556	12/26/95	Elliot, et al.			
AD	5,518,885	05/21/96	Raziuddin, et al.			
AE	5,527,528	06/18/96	Allen, et al.			
AF	5,798,266	08/25/98	Quay, et al.			
AG	5,914,238	06/22/99	Keesee, et al.			
AH	5,763,415	06/09/98	Sukamar			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
AI	WO 97/05898	02/20/97	PCT			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
AJ	Arteaga et al, J Nat Cancer Inst. Jan. 6, 199; vol. 91 no. 1: 46-53					
AK	Barnes & Masood. "Potential value of hormone receptor assay in carcinoma in situ of breast" Am J. Cancer Prevention 11/90					
AL	Berntsen, et al. "Influence of Treatment with Aminoglutethimide on Plasma and Red-Blood-Cell Glutathione Status in Breast Cancer Patients." Cancer Chemother Pharmacol. 1998. Vol 42, pages 46-52.					
AM	Boccuzzi, et al. "Breast Duct Fluid Dehydroepiandrosterone sulphate in Fibrocystic Disease." European J. Cancer and Clinical Oncology. August 1987. Vol 23, pages 1099-1102					
AN	Buzdar, J Clin Oncol. 1998; Jan 16(1): 348-53					
AO	"Cancer detection techniques shown." Santa Barbara News Press 8/3/71					
AP	Cassels, "New test may speed breast cancer detection." The Medical Post March 20, 1973					
AQ	Ernster, et al. "Benign and malignant breast disease: initial study results of serum and breast fluid analyses of endogenous estrogens." J. Nat. Cancer Inst. vol 79 no. 5					
AR	Fabian, et al. "Biomarker and cytologic abnormalities in women at high and low risk for breast cancer" J. of Cellular Biochemistry 17G:153-160 (1993)					
AS	Fabian, et al. "Prevalence of abnormal biomarkers in fine needle breast aspirates in high risk populations." 1993 Proc. Ann Meeting Am Assoc. Cancer Res. 34: Abstract 1556					
AT	Fabian. "Who should receive which selective estrogen receptor modulator for prevention of breast cancer" The Breast Journal vol 5, no 3, 1999 211-214					
AU	"Finding asymptomatic breast cancer." Medical World News July 23, 1971					
AV	Fryckberg, et al. "Ductal carcinoma in situ of the breast. Surgery" Gynecology & Obstetrics 10/93 vol 177					
AW	Head, et al. "Assessment of immunologic competence and host reactivity against tumor antigens in breast cancer with vaccines." vol. 690 of the Annals of the NY Academy of Sciences 8/12/93					
AX	Imayama, et al. "Presence of elevated carcinoembryonic antigen on absorbent disks applied to nipple are of breast carcinoma patients." Cancer Sept 15, 1996 vol 78 no. 6					

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		Filing Date: June 30, 2003	Group: Unknown
AY	"Breast Fluid cells help in early cancer detection" JAMA May 7, 1973; vol 224, no. 6 pgs 823-827		
AZ	Osborne, New England J. Med. 1998; vol. 339, no.22: 1609-1618		
BA	King, et al. "Analytic studies of foam cells from breast cancer precursors." Cytometry 5:124-130 (1984)		
BB	King, et al. "Cellular composition of the nipple aspirate specimen of breast fluid." AJCP vol 64 Dec 1975 pp 728-738		
BC	Kristensen, et al. "A rare CYP19 (aromatase) variant may increase the risk of breast cancer." Pharmacogenetics. 1998. Vol. 8, pages 43-48		
BD	Lobsenz. "A new way to detect breast cancer early." Good House Keeping Jan 1975		
BE	Lu et al. "The Effects of Aromatase Inhibitors and Antiestrogens in the Nude Mouse Model." Breast Cancer Research and Treatment 1998. Vol 50, pages 63-71		
BF	Masood & Johnson. "The value of imprint cytology in cytochemical detection of steroid hormone receptors in breast cancer." AJCP vol 87 No 1 pp 30-36		
BG	Masood et al. Breast Health Challenges and Promises." J. Florida M.A. Aug/Sept 1996/Vol. 83, No. 7 pp459-465		
BH	Masood. "Fluorescent cytochemical detection of estrogen and progesterone receptors in breast fine-needle aspirates." AJCP Jan 1991		
BI	Masood. "The missing link: a 'pap smear' for early breast cancer detection and prevention." The Breast Journal, vol 5 number 1, 1999 pp. 1-2		
BJ	Nass, et al. "Breast cancer biology blossoms in the clinic." Nature Medicine vol 4 No. 7 July 1998		
BK	Norton, L Semin Oncol. 1997: Aug 24(4) Suppl 10; S10-3-S10-10		
BL	O'Regan et al, 1999 Am. Coll Surgeons vol. 188; no. 6 June 1999:678-684		
BM	Papanicolaou et al. "Exfoliative cytology of the human mammary gland and its value in the diagnosis of cancer and other diseases of the breast." Cancer March-April 1958, 11(2): 377-409		
BN	Pertschuk et al. "Estrogen receptor immunochemistry in endometrial carcinoma." Gynecologic oncology 63, 28-33 (1996) pp 28-33		
BO	Petrakis & King. "Genetic markers and cancer epidemiology." Cancer April supp 1977 vol 39 pp1861-1866		
BP	Petrakis et al. "Epithelial dysplasia in nipple aspirates of breast fluid: association with family history and other breast cancer risk factors ." JNCI vol 68 no. 1 Jan 1982		
BQ	Petrakis, "Nipple aspirate fluid in epidemiologic studies of breast disease." Epidemiologic reviews vol 15 no. 1 1993		
BR	Rose et al. "A Comparison of Serum and Breast Duct Fluid Immunoassayable prolactin and Growth Hormon Woman and and Patients with Cystic Breast Disease." Cancer, 01 December, 1987. Vol 60. No. 11, pages 2761-2765.		
BS	Sartorius et al. "The Biochemistry of breast cyst fluids and duct secretions." Breast Cancer Research and Treatment 35:255-266 1995		
BT	Sauter et al. "Prostate specific antigen levels in nipple aspirate fluid correlate with breast cancer risk" Cancer Epidemiology vol. 5, 967-970, Dec. 1996		
BU	Strah & Love. "The in situ carcinomas of the breast." JAMWA vol 47 No 5 Sept /Oct 1992		
BV	Sukumar & McKenzie, "Breast cancer prevention strategies for the twenty first century" Molecular Medicine Today Nov. 1996		
BW	Sukumar et al. "Independent molecular pathways in initiation and loss of hormone responsiveness of breast carcinomas." Science 22 April 1988		
BX	Tankanow, Am J Health Syst. Pharm 1998: Sept. 1 (55/17) pp. 1777-91		
BY	Wrensch, et al. "Breast cancer risk associated with abnormal cytology in nipple aspirates of breast fluid and prior history of breast biopsy." Am J. of Epidemiology vol 137 no. 8 1993		
BZ	Wynder et al. "Breast Secretion in Finnish Women: a metabolic epidemiologic study," Cancer 47: 1444-1450, 1981		
CA	Wynder et al, "Prolactin Oestrogen, and Lipids in Breast Fluid." The Lancet 22 October 1977. Vol. 2 No. 8043, pages 840-842.		

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		SNEIGE et al., "Fine-Needle Aspiration Cytology Of Ductal Hyperplasia With And Without Atypia And Ductal Carcinoma In Situ", Human Pathology, Vol. 25, No. 5, pp 485-492, May 5, 1996	
		KING et al., "Cellular Composition Of The Nipple Aspirate Specimen Of Breast Fluid I. The Benign Cells", American Journal Of Clinical Pathology, Vol. 64, No. 6, pp 728-745, 1975	
		PORTER-JORDAN and LIPPMAN, K., "Overview Of The Biological Markers Of Breast Cancer", Hematology – Oncology Clinics Of North America, Vol. 8, No. 1, pp 73-100, February 1994	
		BAE, H.W. et al., "Characterization Of The Promoter Region Of The Human Transforming Growth Factor-Beta Type II Receptor Gene", Journal of Biological Chemistry, Vol. 270, No. 49, pp. 29460-29468, December 8, 1995	
		MUNOZ-ANTONIA T. et al., "A Mutation In The Transforming Growth Factor Beta Type II Receptor Gene Promoter Associated With Loss Of Gene Expression", Cancer Research, Vol. 56, pp 4831-4835, November 1, 1996	
		Supplemental Partial European Search Report, EP 00 90 4589, March 25, 2003	

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____ AA	4,202,329	05/13/80	Kortum		
____ AB	4,365,632	12/28/82	Kortum		
____ AC	4,981,692	01/01/91	Popescu et al.		
____ AD	5,763,415	06/09/98	Sukumar		
FOREIGN PATENT DOCUMENTS					
	Document No.	Date	Country	Class	Translation (Yes/No)
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)					
____ AE	Fisher et al., "Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant breast and bowel project P-1 study" Journal of the National Cancer Institute (1998) 90(18):1371-1388.				
____ AF	Goodson et al., "Discharges and secretions of the nipple" The Breast: Comprehensive Management of Benign & Malignant Diseases, Bland & Kirby, Eds., W.B. Saunders, Philadelphia, Second Edition, Chapter 4, (1998) 2:51-74.				
____ AG	King et al., "Nipple aspirate cytology for the study of breast cancer precursors" Journal of the National Cancer Institute (1983) 71:1115-1121.				
____ AH	Love et al., "Breast-duct endoscopy to study stages of cancerous breast disease" The Lancet (1996) 348:997-999.				
____ AI	Papanicolaou et al., "Exfoliative cytology of the human mammary gland and its value in the diagnosis of cancer and other diseases of the breast: Cancer (1958) 11(2):377-409.				
____ AJ	Sartorius et al., "Cytologic evaluation of breast fluid in the detection of breast disease" Journal of the National Cancer Institute (1977) 59(4):1073-1078.				
____ AK	Sauter et al., "Nipple aspirate fluid: A promising non-invasive method to identify cellular markers of breast cancer risk" British Journal of Cancer (1997) 76(4):494-501.				
____ AL	Wrensch et al., "Breast cancer incidence in women with abnormal cytology in nipple aspirates of breast fluid" American Journal of Epidemiology (1992) 135(2):130-141.				
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DB	Zippin & Petrakis, "Identification of high risk groups in breast cancer." Cancer vol 28 pp 1381-1387 Dec 1971		
DC	"'Pap' test for breast cancer" a periodical clipping		
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